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MediPurpose Pte. Ltd.
Traditional 510(k) - MediPlus-Foam™ AG Dressings

SEP - 1 2011

510(k) Summary

Owner's Information:	MediPurpose, Pte. Ltd. 3850 Holcomb Bridge Road, Suite 350 Norcross, GA 30092
Contact Person:	Julie Stephens, President/Consultant Regulatory Resources Group, Inc.
510(k) Number:	
Date Prepared:	December 2010
Trade/Proprietary Name:	MediPlus-Foam™ AG Dressings MediPlus-ComfortFoam™ AG Dressings MediPlus-SuperFoam™ AG Dressings
Common Name:	Silver Containing Wound Dressing
Classification Name:	Dressing, wound, drug
Class:	Unclassified, Pre-Amendment
Product Code:	FRO
Legally Marketed Predicate Devices:	Smith & Nephew Inc., Allevyn Ag Dressings, 510(k) # K063835

Device Description:

The MediPlus-Foam™ AG Dressings product line is a multi-layered, sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth elastic and breathable PU foam sandwiched in between a breathable PU film and a silver net layer acting as an antimicrobial barrier. The product line is available in different sizes. The MediPlus-SuperFoam™ AG Dressings product line has slightly thicker PU foam and is easier to bend for covering wound areas such as elbows or heels.

The MediPlus-ComfortFoam™ AG Dressings is a multi-layered, sterile highly absorbing open cell hydrophilic wound dressing composed of a thick soft, smooth elastic and breathable PU foam sandwiched in between a breathable PU film coated with acrylic adhesive and extends to act as a border adhesive film to allow application without need for secondary dressing or fixation bandage. The silver net layer acts as an antimicrobial barrier. MediPlus-ComfortFoam AG is useful for body sites where applying a secondary dressing or fixation bandage is not practicable or not desired by the user.

MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings are used as an antimicrobial barrier for partial and full-thickness wounds such as burns, donor sites and graft recipient sites that are judged to be at risk from infection. The product features include: managing moisture level in the wound environment, controlled silver release, and the product mesh facilitates the passage of fluids/exudates through the dressing into the PU foam for adsorption. The dressings can remain on the wound for five to seven (5-7) days dependent on the amount of wound exudates.

510(k) Summary

Intended Use:

The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
- Pressure Sores
- Donor Sites
- Surgical Incisions
- Surgical Excisions
- Burns (1st and 2nd degree)

Similarities and Differences of the Proposed Devices to the Predicate Devices:

Similarities
The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings have the same basic technology characteristics for silver containing wound dressings. The features and benefits of using silver containing wound dressings are the same as the predicate and the indications for use are the same. The materials are comparable in that the silver ions are incorporated in the dressing and the plastics used against the wound bed are proven biocompatible.

Differences
The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings utilize some of the same materials, specifically the use of plastics. The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings comply with testing requirements of the recognized biocompatibility standard (see Section C).

Conclusion:

The MediPlus-Foam AG, MediPlus-ComfortFoam AG, and MediPlus-SuperFoam AG Dressings have the same principles of operation, intended use, and technological characteristics as the predicate device. Testing was completed for biocompatibility and antimicrobial effectiveness and the testing reports are contained in the 510(k) documentation (see Section C).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MediPurpose Pte., Ltd.
% Regulatory Resources Group, Inc.
Ms. Julie Stephens
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

SEP - 1 2011

Re: K110062
Trade/Device Name: MediPlus-Foam™ AG Dressings
MediPlus-ComfortFoam™ AG Dressings
MediPlus-SuperFoam™ AG Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 01, 2011
Received: August 02, 2011

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Director

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110062

Device Name: MediPlus-Foam™ AG Dressings
MediPlus-ComfortFoam™ AG Dressings
MediPlus-SuperFoam™ AG Dressings

Indications for Use:

The MediPlus-Foam™ AG, MediPlus-ComfortFoam™ AG, and MediPlus-SuperFoam™ AG Dressings are indicated for exudate absorption and the management of partial to full thickness wounds. Some typical wounds are:

- Ulcers (venous, arterial, diabetic)
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- Surgical Excisions
- Burns (1st and 2nd degree)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110062

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